

PTO/SB/17 (10-04)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180

Complete if Known

Application Number	09/633,034
Filing Date	August 4, 2000
First Named Inventor	Tsang, et al.
Examiner Name	L.R. Helms
Art Unit	1642
Attorney Docket No.	072771.0106

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit Account Number
Deposit Account Name

02-4377

Baker Botts L.L.P.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
1001	2001	Utility filing fee	
1002	2002	Design filing fee	
1003	2003	Plant filing fee	
1004	2004	Reissue filing fee	
1005	2005	Provisional filing fee	

SUBTOTAL (1) (\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid	
-20	=	X	=0	
Independent Claims	-3	=	X	=0
Multiple Dependent			X	=0

Large Entity Fee Code	Small Entity Fee Code	Fee Description
1202	2202	Claims in excess of 20
1201	2201	Independent claims in excess of 3
1203	2203	Multiple dependent claim, if not paid
1204	2204	** Reissue independent claims over original patent
1205	2205	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
1051	2051	Surcharge - late filing fee or oath	
1052	2052	Surcharge - late provisional filing fee or cover sheet	
1053	1053	Non-English specification	
1812	1812	For filing a request for <i>ex parte</i> reexamination	
1804	1804	Requesting publication of SIR prior to Examiner action	
1805	1805	Requesting publication of SIR after Examiner action	
1251	2251	Extension for reply within first month	
1252	2252	Extension for reply within second month	
1253	2253	Extension for reply within third month	
1254	2254	Extension for reply within fourth month	
1255	2255	Extension for reply within fifth month	
1401	2401	Notice of Appeal	
1402	2402	Filing a brief in support of an appeal	
1403	2403	Request for oral hearing	
1451	2451	Petition to institute a public use proceeding	
1452	2452	Petition to revive - unavoidable	
1453	2453	Petition to revive - unintentional	
1501	2501	Utility issue fee (or reissue)	
1502	2502	Design issue fee	
1503	2503	Plant issue fee	
1460	2460	Petitions to the Commissioner	
1807	2807	Processing fee under 37 CFR 1.17(q)	
1806	2806	Submission of Information Disclosure Stmt	180
8021	28021	Recording each patent assignment per property (times number of properties)	
1809	2809	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	2810	For each additional invention to be examined (37 CFR 1.129(b))	
1801	2801	Request for Continued Examination (RCE)	
1802	2802	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180

SUBMITTED BY

(Complete if applicable)

Name (Print/Type)

Lisa B. Kole

Registration No.
(Attorney/Agent)

35,225

Telephone

212-408-2500

Signature

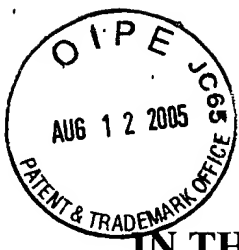
Date

08/10/2005

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



A33081-R 072771.0106
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tsang et al.

Serial No.: 09/633,034

Examiner: Helms, L.R.

Filed : August 4, 2000

Group Art Unit: 1642

For : MONOCLONAL ANTIBODIES AGAINST HUMAN COLON CARCINOMA-
ASSOCIATED ANTIGENS AND USES THEREFOR

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited on August 12 2005 with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

08/12/2005 HTECKLU1 00000013 09633034

01 FC:1806

180.00 per Lisa B. Kole

35,225

Attorney Name

PTO Registration No.

August 12 2005

Signature

Date of Signature

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the document listed below be considered by the Examiner and made of record in the above-referenced application.

NY02:524047.4

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

U.S. PATENT DOCUMENTS								
*Exam. Initial.	No.		Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.
	11		6,346,249	February 12, 2002	Barbas III et al.			4/4/2000.
	12		6,342,587	January 29, 2002	Barbas III et al.			10/22/1999
	28		5,958,412	Sept. 28, 1999	Welt et al.			6/4/1997
	33		5,712,369	January 27, 1998	Welt et al.			2/2/1996.
	39		5,643,550	July 1, 1997	Welt et al.			9/27/1994
	47		5,160,723	November 3, 1991	Welt et al.			3/18/ 1991.

FOREIGN PATENT DOCUMENTS								
Exam Initial	No.		Document No.	Date	Country	Class	Subclass	Translation Yes No

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	1	Chong, G., F. T. Lee, et al. (2005). "Phase I Trial of 131I-huA33 in Patients with Advanced Colorectal Carcinoma." Clin Cancer Res 11(13): 4818-26.
	2	Koppe, M. J., R. P. Bleichrodt, et al. (2005). "Radioimmunotherapy and colorectal cancer." Br J Surg 92(3): 264-276.
	3	Mallegol, J., G. van Niel, et al. (2005). "Phenotypic and functional characterization of intestinal epithelial exosomes." Blood Cells Mol Dis 35(1): 11-16.
	4	Scott, A. M., F. T. Lee, et al. (2005). "A Phase I Trial of Humanized Monoclonal Antibody A33 in Patients with Colorectal Carcinoma: Biodistribution, Pharmacokinetics, and Quantitative Tumor Uptake." Clin Cancer Res 11(13): 4810-4817.
	5	Deckert, P. M., W. G. Bornmann, et al. (2004). "Specific tumour localisation of a huA33 antibody--carboxypeptidase A conjugate and activation of methotrexate-phenylalanine." Int J Oncol 24(5): 1289-95.
	6	Joosten, C. E., L. S. Cohen, et al. (2004). "Glycosylation profiles of the human colorectal cancer A33 antigen naturally expressed in the human colorectal cancer cell line SW1222 and expressed as recombinant protein in different insect cell lines." Biotechnol Prog 20(4): 1273-9.
	7	Deckert, P. M., C. Renner, et al. (2003). "A33scFv-cytosine deaminase: a recombinant protein construct for antibody-directed enzyme-prodrug therapy." Br J Cancer 88(6): 937-9.
	8	Mao, Z., S. Song, et al. (2003). "Transcriptional regulation of A33 antigen expression by gut-enriched Kruppel like factor." Oncogene 22(28): 4434-43.
	9	Welt et al., 2003, Phase I Study of Anticolon Cancer Humanized Antibody A331. Clinical Cancer Res. 9(4):1338-1346.

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	10	Welt, S., G. Ritter, et al. (2003). "Preliminary report of a phase I study of combination chemotherapy and humanized A33 antibody immunotherapy in patients with advanced colorectal cancer." Clin Cancer Res 9(4): 1347-53.
	13	Johnstone, C. N., S. J. White, et al. (2002). "Analysis of the regulation of the A33 antigen gene reveals intestine-specific mechanisms of gene expression." J Biol Chem 277(37): 34531-9.
	14	Orlova, A., J. Hoglund, et al. (2002). "Comparative biodistribution of the radiohalogenated (Br, I and At) antibody A33. Implications for in vivo dosimetry." Cancer Biother Radiopharm 17(4): 385-96.
	15	van Niel, G. and M. Heyman (2002). "The epithelial cell cytoskeleton and intracellular trafficking. II. Intestinal epithelial cell exosomes: perspectives on their structure and function." Am J Physiol Gastrointest Liver Physiol 283(2): G251-5.
	16	Barendswaard, E. C., J. L. Humm, et al. (2001). "Relative therapeutic efficacy of (125)I- and (131)I-labeled monoclonal antibody A33 in a human colon cancer xenograft." J Nucl Med 42(8): 1251-6.
	17	Lee, F. T., A. Rigopoulos, et al. (2001). "Specific localization, gamma camera imaging, and intracellular trafficking of radiolabelled chimeric anti-G(D3) ganglioside monoclonal antibody KM871 in SK-MEL-28 melanoma xenografts." Cancer Res 61(11): 4474-82.
	18	Ritter, G., L. S. Cohen, et al. (2001). "Serological analysis of human anti-human antibody responses in colon cancer patients treated with repeated doses of humanized monoclonal antibody A33." Cancer Res 61(18): 6851-9.
	19	van Niel, G., G. Raposo, et al. (2001). "Intestinal epithelial cells secrete exosome-like vesicles." Gastroenterology 121(2): 337-49.
	20	Abud, H. E., C. N. Johnstone, et al. (2000). "The murine A33 antigen is expressed at two distinct sites during development, the ICM of the blastocyst and the intestinal epithelium." Mech Dev 98(1-2): 111-4.

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	21	Deckert, P. M., A. Jungbluth, et al. (2000). "Pharmacokinetics and microdistribution of polyethylene glycol-modified humanized A33 antibody targeting colon cancer xenografts." <i>Int J Cancer</i> 87(3): 382-90.
	22	Johnstone, C. N., N. C. Tebbutt, et al. (2000). "Characterization of mouse A33 antigen, a definitive marker for basolateral surfaces of intestinal epithelial cells." <i>Am J Physiol Gastrointest Liver Physiol</i> 279(3): G500-10.
	23	Rader, C., G. Ritter, et al. (2000). "The rabbit antibody repertoire as a novel source for the generation of therapeutic human antibodies." <i>J Biol Chem</i> 275(18): 13668-76.
	24	Ruan, S., J. A. O'Donoghue, et al. (2000). "Optimizing the sequence of combination therapy with radiolabeled antibodies and fractionated external beam." <i>J Nucl Med</i> 41(11): 1905-12.
	25	Sakamoto, J., H. Kojima, et al. (2000). "Organ-specific expression of the intestinal epithelium-related antigen A33, a cell surface target for antibody-based imaging and treatment in gastrointestinal cancer." <i>Cancer Chemother Pharmacol</i> 46 Suppl: S27-32.
	26	Barendswaard, E. C., J. A. O'Donoghue, et al. (1999). "131I radioimmunotherapy and fractionated external beam radiotherapy: comparative effectiveness in a human tumor xenograft." <i>J Nucl Med</i> 40(10): 1764-8.
	27	Miyazono, Y., Y. Kamogawa, et al. (1999). "Effect of B7.1-transfected human colon cancer cells on the induction of autologous tumour-specific cytotoxic T cells." <i>J Gastroenterol Hepatol</i> 14(10): 997-1003.
	29	Barendswaard, E. C., A. M. Scott, et al. (1998). "Rapid and specific targeting of monoclonal antibody A33 to a colon cancer xenograft in nude mice." <i>Int J Oncol</i> 12(1): 45-53.
	30	Burgess, A. W. (1998). "Growth control mechanisms in normal and transformed intestinal cells." <i>Philos Trans R Soc Lond B Biol Sci</i> 353(1370): 903-9.

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	31	Moritz, R. L., G. Ritter, et al. (1998). "Micro-sequencing strategies for the human A33 antigen, a novel surface glycoprotein of human gastrointestinal epithelium." J Chromatogr A 798(1-2): 91-101.
	32	Tio, T. L. (1998). "Diagnosis and staging of esophageal carcinoma by endoscopic ultrasonography." Endoscopy 30 Suppl 1: A33-40.
	34	Catimel, B., M. Nerrie, et al. (1997). "Kinetic analysis of the interaction between the monoclonal antibody A33 and its colonic epithelial antigen by the use of an optical biosensor. A comparison of immobilisation strategies." J Chromatogr A 776(1): 15-30.
	35	Heath, J. K., S. J. White, et al. (1997). "The human A33 antigen is a transmembrane glycoprotein and a novel member of the immunoglobulin superfamily." Proc Natl Acad Sci U S A 94(2): 469-74.
	36	Ji, H., R. L. Moritz, et al. (1997). "Electrophoretic analysis of the novel antigen for the gastrointestinal-specific monoclonal antibody, A33." Electrophoresis 18(3-4): 614-21.
	37	Ritter, G., L. S. Cohen, et al. (1997). "Characterization of posttranslational modifications of human A33 antigen, a novel palmitoylated surface glycoprotein of human gastrointestinal epithelium." Biochem Biophys Res Commun 236(3): 682-6.
	38	Tschmelitsch, J., E. Barendswaard, et al. (1997). "Enhanced antitumor activity of combination radioimmunotherapy (131I-labeled monoclonal antibody A33) with chemotherapy (fluorouracil)." Cancer Res 57(11): 2181-6.
	40	No Author listed. (1996). "MoAb A33 shows promise in targeting colon cancer for radioimmunotherapy." Oncology (Huntingt) 10(4): 553.
	41	Antoniw, P., A. P. Farnsworth, et al. (1996). "Radioimmunotherapy of colorectal carcinoma xenografts in nude mice with yttrium-90 A33 IgG and Tri-Fab (TFM)." Br J Cancer 74(4): 513-24.

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33081-R 072771.0106	Serial No. 09/633,034
	Applicant Tsang <i>et al.</i>	
	Filing Date August 4, 2000	Group 1642
	Examiner Helms, L.R.	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	42	Daghighian, F., E. Barendswaard, et al. (1996). "Enhancement of radiation dose to the nucleus by vesicular internalization of iodine-125-labeled A33 monoclonal antibody." J Nucl Med 37(6): 1052-7.
	43	Welt, S., A. M. Scott, et al. (1996). "Phase I/II study of iodine 125-labeled monoclonal antibody A33 in patients with advanced colon cancer." J Clin Oncol 14(6): 1787-97.
	44	King, D. J., P. Antoniow, et al. (1995). "Preparation and preclinical evaluation of humanised A33 immunoconjugates for radioimmunotherapy." Br J Cancer 72(6): 1364-72.
	45	Scott, A. M., E. Rosa, et al. (1995). "In vivo imaging and specific targeting of P-glycoprotein expression in multidrug resistant nude mice xenografts with [125I]MRK-16 monoclonal antibody." Nucl Med Biol 22(4): 497-504.
	46	Welt et al., 1994, Phase I/II Study of Iodine 131-Labeled Monoclonal Antibody A33 in Patients With Advanced Colon Cancer. J. Clin. Oncol. 12:1561-71

NY02:524633.3

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.